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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/419,305

10/15/99

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HM12/1025

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WASHINGTON DC 20004

EXAMINER

PROUTY, R

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

10/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/419,305

Applicant(s)
Maryta t al.

Examiner
Rebecca Prouty

Group Art Unit
1652



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1 is/are pending in the applicat
- Of the above, claim(s) _____ is/are withdrawn from consideration
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☒ received in Application No. (Series Code/Serial Number) 08/505,448
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,976,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recite variants of the enzyme of SEQ ID NO:1.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim one is indefinite and confusing in the recitation of "which contains one or more amino acid residues selected partially from SEQ ID NO:3 and SEQ ID NO:4" as it is unclear if this means the sequence must contain both SEQ ID NO:3 and SEQ ID NO:4, either of SEQ ID NO:3 or SEQ ID NO:4, or only some fragment of one or both of these sequences. If the last of these is intended, this recitation has essentially no meaning as all proteins are comprised of amino acids and will contain at least one amino acid residue that is found in SEQ ID NO:3 or SEQ ID NO:4.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the enzyme of SEQ ID NO:1 or enzymes encoded by genes which will hybridize to

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SEQ ID NO:2 under specific conditions, does not reasonably provide enablement for any enzyme with the claimed properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

These claims are so broad as to encompass any enzyme with the claimed physicochemical properties (given the broadest reasonable interpretation of the scope of the phrase "which contains one or more amino acid residues selected partially from SEQ ID NO:3 and SEQ ID NO:4" as discussed above), including any naturally occurring enzymes with the claimed properties, fragments thereof which retain enzymatic activity and all functionally equivalent variants of such a naturally occurring enzyme. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of enzymes broadly encompassed by the claims. Neither the specification nor the prior art provide any guidance regarding additional sources of naturally occurring enzymes with the claimed properties. One of ordinary skill in the art would clearly be aware that enzymes with similar enzymatic activities can be highly diverse and often bear little or no homology to one another. This is particularly true where the enzymes are found within organisms which are evolutionarily

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highly diverse but is not uncommon even for two enzymes with the same organism or for enzymes encoded within evolutionarily similar organisms. As such one of ordinary skill in the art would be unable to isolate such enzymes and their corresponding genes without undue experimentation to find a suitable source. Furthermore, the specification fails to provide enablement for all variants and fragments of the enzyme of SEQ ID NO: 1. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence and the amino acid sequence of a single enzyme with the claimed properties.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of

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success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any enzyme with the claimed physicochemical properties because the specification does not establish: (A) regions of the protein structure which may be modified without effecting activity; (B) the general tolerance of such enzymes to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any enzyme with the claimed physicochemical properties. The scope of the claims must bear a

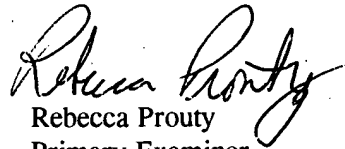
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reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of enzymes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Rebecca Prouty
Primary Examiner
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